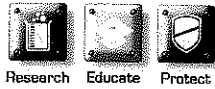


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Research Educate Protect

Meeting with the White House
Office on Information and Regulatory Affairs (OIRA)
and
Office of Management and Budget (OMB)
(RIN#0910-AG38)

December 7, 2015

Cheryl Richter, Philip Roseman and Chris Imlah
National Vapers Club Board of Directors

12/7/2015

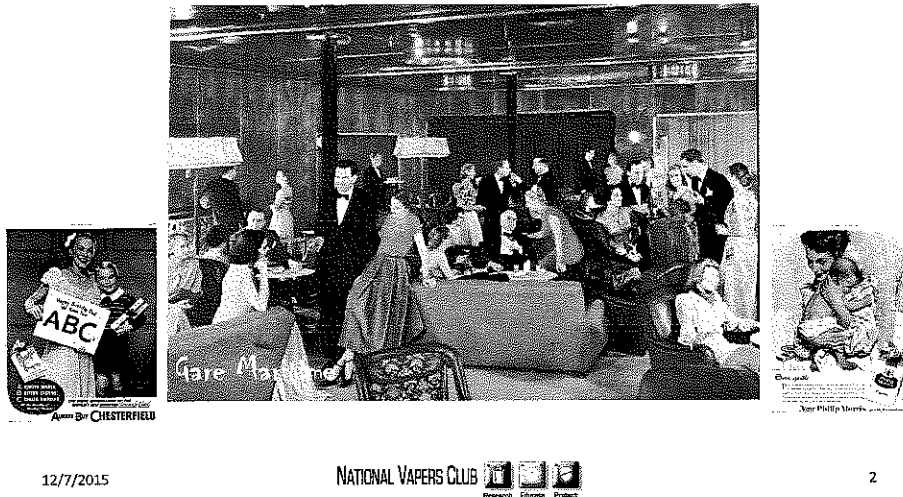
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1

When we were kids, everyone smoked.
Ironically, the same year I was born, the first electronic
cigarette was patented – but never brought to market.



I started smoking when I was 13. When I was growing up,
practically everyone I knew smoked. After more than 30 years,
and trying everything I could to quit, I never had another
cigarette nor did I want one once I bought my first e-cig. It was a
miracle. I set out to tell every smoker I knew about e-cigarettes.
With a family friend who had the same experience at the same
time, we started a service for our friends and family who
smoked.

Here we are, 50 years later...

"Cigarette smoking is responsible for more than 480,000 deaths per year in the United States, including an estimated 42,000 deaths resulting from secondhand smoke exposure. This is about one in five deaths annually, or 1,300 deaths every day."

-CDC

"In the past 3 years I lost a good friend, two aunts and my father to smoking related illnesses. The pain of their loss has fueled my passion to keep vaping easily accessible to all adult smokers."

-Cheryl Richter



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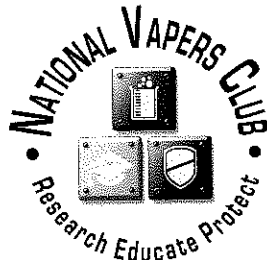
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We all know someone who has died from smoking, many close family members. In the past 3 years I lost a good friend, two aunts and my father to smoking related illnesses. The pain of their loss has fueled my passion to keep vaping easily accessible to all adult smokers.

Cheryl L. Richter



Co-Owner



Secretary/Treasurer



Co-Chair NY Chapter

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In addition to being a business owner, I spend a tremendous amount of time as a volunteer for two vaping groups because I believe so strongly in the importance of vaping products. I'm the Secretary Treasurer of National Vapers Club. We promote vaping advocacy, education and research through grassroots fundraising efforts from vaping consumers and small businesses. I am also the co-chair of the NY chapter of SFATA, the Smoke-free Alternatives Trade Association.

My business, Cherry Vape, designs accessories and components for vaping products which are manufactured in New York and distributed globally, we have a brick & mortar store in Port Chester NY called Vape Den, and we also have a line of e-liquid called Nicter.

Vaping Industry: Ex-Smoking Entrepreneurs – NOT Big Tobacco

- 2007 – only “ciga-likes” on the market
- Victims of tobacco became vapers
- Vapers became hobbyists. Made “modifications”:
 - Added safety features (temperature control, safety shut offs, short circuit protection)
 - Longer lasting
 - More appealing
 - Highly effective
 - Safety protocols in e-liquid manufacturing
- Hobbyists became entrepreneurs—owners of:
 - Manufacturing plants, e-liquid labs, vape shops, distribution centers
- Entrepreneurs are a unified community with Anti-Big Tobacco sentiment
- Consumers and industry passionate in mission to help smokers

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In 2009, I was a freelance copywriter, and my business partner was a carpenter. Back then e-cigarettes were not common, and they frankly didn't work very well. The batteries didn't last, they leaked, and their vapor production was weak. But we knew there was something to it.

Ours became a viable business when we started designing accessories, and created a line of e-liquid. We were not unique, and hobbyists around the world started modifying flashlights, building boxes, adding safety features...That's how this industry was born.

Our story is typical of the thousands of other vapers who were engineers and mechanics, carpenters, creatives and tinkerers, who discovered e-cigs and wanted to make them better.

It's the victims of tobacco who are the entrepreneurs that made vaping products safer, longer lasting, more appealing and incredibly effective. What you need to know about us and thousands of other vaping product manufacturers and vape shop owners -- is that we are NOT BIG TOBACCO. We are ANTI-tobacco—we are entrepreneurs and micro and small business owners who are very passionate about the benefits of vaping – how it affected us, our families, friends, communities and customers.

As new technology developed and the industry matured, vapor products became safer. Testing and safety protocols for e-liquid manufacturing have become standard practice. Mods went from modified flashlights to having electronic components with short circuit protection and temperature control. More powerful batteries improved vapor production and has allowed people to **step down** their nicotine levels, often going from 2.4% by volume down to .3% or none.

All of these product improvements happened after the 2007 Substantial Equivalent grandfather date.

Vaping Products are for Adult Smokers



"Regular use of electronic cigarettes amongst children and young people is rare and is confined almost entirely to those who currently or have previously smoked."¹

1. Action on Smoking and Heath, April 2014

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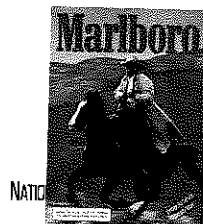
Our mission is to get the older, hard-core generation OFF cigarettes. In this NON-tobacco industry, there is no evil group sitting around a board table saying "how do we get kids hooked on vaping"? In fact, according Action on Smoking and Heath, **"Regular use of electronic cigarettes amongst children and young people is rare and is confined almost entirely to those who currently or have previously smoked."**

We Don't Market to Children

AGE TO VAPE
18
WE CHECK ID

MUST BE 18 OR OLDER
TO ENTER AND SHOW
A VALID ID.
FAKE IDs WILL BE
CONFISCATED AND
THE POLICE WILL BE
CALLED

(because Big T marketed to Us)



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Having been marketed to as kids ourselves, we know what it looks like, and our mission is NOT to hook a new generation on nicotine. We believe there should be a national age restriction of over 18 on the sale of vapor products in the US. It's a no-brainer. Yes, it's true, we REALLY don't want another generation to grow up addicted to nicotine. The industry was self-regulating this before it became law in almost every state.

Our mission is to get the older, hard-core generation OFF cigarettes.

According to SmokingAnswers.com:

"One of the harmful effects of smoking is the damage it does to your palate. Smoking deadens your taste buds and reduces the tastes you experience. Once you quit smoking, that steak is going to be juicier, that apple tastier and that candy bar a little sweeter."

Once a vaper gets used to nicotine delivered via flavors, they react negatively to the stench of cigarettes. Flavors help keep them from smoking.

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Al Bender, 68, inspiration for "Al's Cookie" Nicter Flavor based on an actual cookie recipe he liked



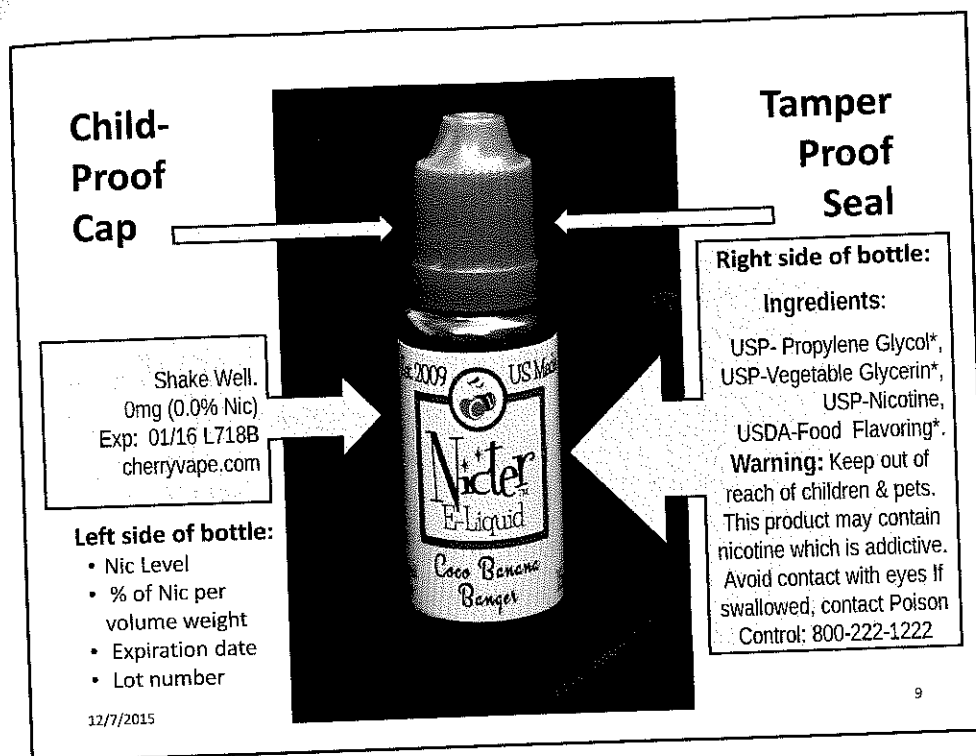
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What you need to understand is how important flavors are to ADULT smokers for vaping to work for them. According to SmokingAnswers.com: "One of the harmful effects of smoking is the damage it does to your palate. Smoking deadens your taste buds and reduces the tastes you experience. Once you quit smoking, that steak is going to be juicier, that apple tastier and that candy bar a little sweeter."

78% of my customers, ALL of whom are adults, moved away from tobacco flavors because tobacco smells and tastes terrible when their taste buds came back. When a vaper has their nicotine cravings satisfied from a fruit or sweet flavor, they find just the smell of tobacco nauseating as non smoker, keeping them even further away from going back to stinky combustible cigarettes. Flavors keep ex-smokers off of combustible cigarettes.

As their taste buds come back, experimenting with a variety of flavors becomes a great pleasure. In fact, my store has to have new flavors every week for our customers who come in to sample otherwise they'll go elsewhere to taste something new.

Our most popular flavors include Crème Brulee, Watermelon and Al's Cookies, a flavor I created for a 69 year old grandfather who was having a hard time finding a flavor he liked well enough to keep away from cigarettes. It's based on a cookie recipe I knew he liked.



E-liquid contains propylene glycol, vegetable glycerin, water-based food flavoring, sometimes distilled water, and sometimes nicotine. We make our e-liquid using USDA flavorings from American companies that have been around for generations. It's the same flavorings that are used everywhere to flavor coffees, ice cream, and liquor and even the air outside of coffee shops.

Our flavorings are free of sugar, salt, alcohol, oil, gluten, diacytel and AP and are purchased Kosher-certified. We use only Kosher Pharma -grade PG and VG, and pharma- grade nicotine. Bottles are child and tamper resistant and include nicotine volume, expiration date, lot number, list of ingredients, and warnings. These are considered typical standards that the trade associations have set for good manufacturing, which the vast majority of businesses follow. Those that don't are called out and eviscerated in the court of public shame on social media and forums.

In other words, that's how the free market today works. The FDA should be working with industry associations to set good business practices.

Kids love their parents
more than flavors.



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You know what kids love more than flavors? They're parents! And our customers want to be around for their kids. This is Jessica and Andy and their two daughters. This couple along with Jessica's parents, brother, aunts, numerous cousins, and many friends have been tobacco free due to vaping for over 4 years.

This is why we do this.

Of the hundreds of vape business owners I have met, the vast majority started their businesses because vaping made an impact on their lives and they wanted to share it with other smokers. These small business owners are creating jobs. They are paying taxes. They are occupying previously vacant store fronts and warehouses. They are putting roofs over their kids' heads and sending them to college. They are joining the Chambers of Commerce and they are creating and supporting charities. They are good citizens making lives for themselves.

believe that vapor products should be regulated, but we are very critical of why the FDA would choose to

Dr. Michael Siegel,

Professor in the Department of Community Health
Sciences, Boston University School of Public Health

**"These deeming regulations should really be called 'The
Cigarette Protection Act of 2015.'**

They create stringent requirements for electronic cigarettes, while allowing the much more toxic real cigarettes to remain on the market, unencumbered and unchallenged by competing products that are much safer and that could have otherwise transformed the nicotine market away from combustible tobacco products, thus saving thousands of lives.

The regulations will decimate the e-cigarette industry, forcing thousands of small vapor shops and e-cigarette sellers out of business. This will no doubt result in many vapers returning to cigarette smokers and many potential quitters from trying to quit using these products."

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We believe that vapor products should be regulated, but we are very critical of why the FDA would choose to require them to fit into to a regulatory framework designed specifically keep new combustible cigarettes from entering the market. As Dr. Michael Siegel said, "These deeming regulations should really be called "the Cigarette Protection Act of 2015."

Dr. Carl Phillips
Tobacco Harm Reduction Researcher/
Scientific Director of CASAA

"Any normal use of the word [regulation] in the context of products refers to rules for product characteristics, performance standards, manufacturing standards, labeling, and the like, such that a product in the category must meet the rules to be allowed on the market.

FDA's tobacco "regulation" includes almost none of that...

And there may never be, because **the real effect of FDA "regulation" is simply to make it nearly impossible for manufacturers to introduce a new product or even make changes to existing products."**

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Common sense should apply to any product regulation, including ours – is it generally regarded as safe? does it perform as advertised? was it manufactured to quality standards? Is it labeled and packaged correctly? All consumers deserve to know that they are getting what they are promised in the product, and that it has been tested for quality assurance. But that is not what consumers will get in these regulations.

They will get the rug pulled out from under them.

As Dr. Carl Phillips said, **the real effect of FDA "regulation" is simply to make it nearly impossible for manufacturers to introduce a new product or even make changes to existing products."**

These deeming regulations are a purposeful de-facto BAN.

My Company's Cost of PMA

(E-Liquid Only)

70 Flavors + 6 Nicotine Levels = 420 SKU's

Pre-Market Application Costs

(estimated by experts at between \$1M - \$20 each)

@ \$1million each = \$420,000,000.00

@ \$10 million each = \$4,200,000,000.00

@ \$20 million each = \$8,400,000,000.00

2014 Total Company Gross Revenue = **\$560,093.00**

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The FDA estimated a cost of just \$333,554 per PMTA. However mountains of paperwork involved, scientific population-wide studies, physiology studies and requirements for each product to prove its particular value to the improvement of public health (something no other product on the market has to prove) experts estimate it would cost \$1 million to \$20 million per application per product SKU.

To put this in realistic terms – My e-liquid line currently has 70 flavors of 6 nicotine levels each. That's 420 SKUs. At \$20 million each, it would cost me \$8Billion, 400 million dollars to try to keep them legal. AND it would be a gamble because there's nothing to say the FDA would approve any of them.

Who Could Possibly Afford PMA?

- Philip Morris USA (Altria)
- R.J. Reynolds
- Lorillard

If they decide to apply would their applications even be accepted?

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Who Could Possibly Afford PMA?

The FDA's deeming regulations are poised to give the entire e-cig industry to a monopoly of 3 Big Tobacco companies – the very companies Public Health says they want to make obsolete.

The Endgame is In Sight, So Let's Run Towards It, Not Away from It

"Anyone who would ponder the endgame must acknowledge that the continuum of risk exists and pursue strategies that are designed to drive consumers from the most deadly and dangerous to the least harmful forms of nicotine delivery. "

Mitch Zeller, Reflections on the 'endgame' for tobacco control, Sept 2012

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Mitch Zeller speaks of a continuum of risk with e-cigarettes at the lower end just slightly above approved NRTs. Then why is the FDA making it so hard to keep them on the market while combustible cigarettes, the highest on the continuum, are freely available?

According to the CDC

- 3.7% of US adults currently use e-cigarettes
- Among current cigarette smokers who had tried to quit smoking in the past year, more than one-half had ever tried an e-cigarette
- 20.3% who had tried to quit in the past year were current e-cigarette users
- Nearly one in four recent former cigarette smokers (22.0%) currently used e-cigarettes

-CDC/NCHS, October 2015

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According to the CDC, 3.7% US adults currently use e-cigarette and more than half of them have used it to try to stop smoking. 22% of those that recently quit are using e-cigarettes.

This regulation would create a gateway back to smoking for those who are trying, and those who have succeeded.

Consumers Value their Vaping Products

Spending Habits of Vapers:¹

- 95.7% use vaping products exclusively
- 36.2% typically spend \$20-\$50 a month on vapor products
- 37.9% typically spend \$50-100 a month on
- 19.8% spend over \$100
 - Budget on flavors:
 - 54.6% all/almost all
 - 36.5% half or more than half flavors

(Addendum) Vapor Bar, Spending Habits Survey, November 2015

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Clearly vapers perceive value in their vaping products otherwise they wouldn't be buying. In a recent spending survey, those that vape exclusively, 38% spend between \$50-100 a month. 20% spend over \$100 a month. 91% say they spend half to all of that on flavors.

With No Legitimate Way to Get the Vaping Products they Want , What Will Consumers Do?

- Dangerous Consequences of no commercially available, regulated flavors or electronic products:
 - 29.3% would go back to smoking¹
 - 66.1% would mix their own e-liquid¹
- Vibrant Black Market:
 - China poised to take over with no need to comply to US regulations
 - Sub-standard mixing by non-experts = huge problem for public health. Ingredients are readily available at supermarkets/pharmacies and free-base (100%) nicotine easily ordered from China
 - Wire, battery & flashlight modified into electronic cigarettes by non-technical experts
 - No electronic safety (short circuit protection, auto-shut off, temperature control)
 - No way to track or police

1. Vapor Bar, Online Spending Habits, November 2015

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What will they do if they can't buy flavors other than tobacco? This is the scary part. Almost a third will go back to smoking. Two-thirds would mix their own.

DIY'ers will be a HUGE problem for public health. Ingredients for flavors can be found at Walmart (but not the quality that's needed) Pure free-base Nicotine can get shipped easily from China. That will now be in people's homes who don't know how to handle it or store it properly.

People who know nothing about electronics will go on Youtube and learn how to make their own mods with wire and flashlights. There will be no short circuit protection, auto-shut off features or temperature control.

And of course a vibrant, robust Black Market will spring up. There will be no industry association standards, because there will be no industry associations: China will ship direct to consumers, with no quality control or respect for US safety standards. At least now US distributors and vape shop owners demand those standards from their suppliers or they won't carry their products. Although labs would shut down, people could easily sell out of their homes – again, with no quality control or safety protocols.

Tracking it and policing it will be impossible.

In other words, consumers looking to buy electronics and e-liquid would easily be able to do so regardless of any regulations by the US government—and it would be much more dangerous than enacting common sense regulations to which US manufacturers would comply.

Widely Available Vaping Products Appropriate for the Protection of Public Health

The FDA should only require vapor product and e-liquid manufacturers to prove that their products meet safety and product standards in order to demonstrate that they are "appropriate for the protection of the public health":

1. Because of the importance of vaping products as a valuable tool for harm reduction for smokers
2. Because of the almost certain dangers that would be caused by a Black/DIY market
3. Because it will lead vapers and those who are trying to use them to quit back to smoking
4. Because e-cigarettes are poised to save Medicaid billions of dollars, according to State Budget Solutions Policy Analysis (Addendum)

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You should not allow the FDA to require a PMTA for every product SKU because it is harmful to public health. Keeping vaping products widely available is actually appropriate for the protection of public health for four main reasons:

1. Because of the importance of vaping products as a valuable tool for harm reduction for smokers
2. Because of the almost certain dangers that would be caused by a Black/DIY market
3. Because it will lead vapers and those who are using them to try to quit back to smoking
4. Because e-cigarettes are poised to save Medicaid billions of dollars, according to State Budget Solutions Policy Analysis (Addendum)

With No Way to Sell Product, What Will the Vaping Industry Do?

- Hundreds of manufacturing facilities shut down
- 15,000+ vape shops close
- 100,000+ people unemployed
- State and Federal tax revenue eliminated
- Business debt unpaid
- Houses foreclosed
- Childrens' College tuition unpaid
- Futures destroyed

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This de-facto ban would cause the 15,000 small shop owners to close their doors because there would be nothing to sell – no e-liquid and no vaping hardware. If a vape shop employs at least 5 people, that mean 75,000 unemployed vape shop employees. If there are 500 e-liquid manufacturers that employ an average of 10 people each, that's another 5,000 people unemployed. That's not including US hardware manufacturers and distributors – we're looking at an estimated 100,000 unemployed.

The financial and societal implications would be huge:

- **Hundreds of manufacturing facilities shut down**
- **15,000+ vape shops closed/store fronts empty**
- **100,000+ people unemployed**
- **State and Federal tax revenue eliminated**
- **Business debt unpaid**
- **Houses foreclosed**
- **Childrens' College tuition unpaid**
- **Futures destroyed**

FDA's Current Deeming Regulations would ensure:

- Smokers keep smoking
- The smoking rate will increase
- Vapers turn to black/DIY market with no safety standards (causing injuries, poisonings and illness)
- Vaping industry will shut down
- Big Tobacco will get bigger
- People will keep dying from smoking related illnesses
- 9 million vapers, their children, families, friends and doctors will truly believe that our Big government cares more for Big Tobacco and Big Pharma than citizens' lives

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Free-market entrepreneurs discovered an answer to a decades-long problem. Innovation in harm reduction should be supported in its infancy by our government. Not regulated away.

The FDA's proposed regulations would ensure:

- Smokers keep smoking
- The smoking rate will increase
- Vapers turn to black/DIY market with no safety standards (causing injuries, poisonings and illness)
- Vaping industry will shut down
- Big Tobacco will get bigger
- People will keep dying from smoking related illnesses
- 9 million vapers, their children, families, friends and doctors will truly believe that our Big government cares more for Big Tobacco and Big Pharma than citizens' lives

We Believe:

- FDA violates multiple sections of Executive Order 12866, giving OIRA ability to rework FDA's Deeming Regulations for a more sensible approach. (see addendum)
- Regulation should establish uniform manufacturing, safety, and quality control standards for vapor products
- Regulatory bodies can and should work with industry associations for appropriate standards

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Why apply the same punitive regulations to an innovative and entrepreneurial industry that makes products that reduce harm, as you would to the industry that makes a living killing people? The family Tobacco Control Act was meant to be punitive and prevent Big Tobacco from doing further harm to the public, however it would punish US far worse.

Citizens should trust that our government will do what is right by us. Not what is right for Big Tobacco and Big Pharma.

We believe that the FDA violates multiple sections of Executive Order 12866 and ask you to rework the regulations for a more sensible approach that will establish manufacturing, safety and quality control measures, and we ask that you work with the industry for appropriate standards.

Smoking kills ½ million people a year in the US. If there was one thing you could do to really help the American people, it would be to open up the market for vaping products and help lead smokers to this life-changing alternative.

Thank you for listening.